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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/572,853

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Gen-Ichiro Soma

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EXAMINER

MI, QIUWEN

ART UNIT

PAPER NUMBER

1655

MAIL DATE

DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/572,853	<b>Applicant(s)</b> SOMA ET AL.	
	<b>Examiner</b> QIUWEN MI	<b>Art Unit</b> 1655	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 15 April 2011.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 12-14, 16-22, 28, 29 and 39-42 is/are pending in the application.
- 4a) Of the above claim(s) 40-42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 12-14, 16-22, 28, 29 and 39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>2/17/2011; 9/27/2010</u> .                                    | 6) <input type="checkbox"/> Other: _____                          |

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## **DETAILED ACTION**

### **CONTINUED EXAMINATIONS**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/24/2011 has been entered.

Applicant's amendment in the reply filed on 12/27/2010 is acknowledged, and Applicant's election of species "wheat four" filed on 4/15/2011 is acknowledged too. Claims 1-11, 15, 23-27, and 30-38 are cancelled. Claims 12-14, 16-22, 28-29, and 39-42 are pending. Claims 40-42 are withdrawn as they are directed to nonelected species. **Claims 12-14, 16-22, 28-29, and 39 are examined on the merits.**

Any rejection that is not reiterated is hereby withdrawn.

### **Claim Rejections –35 USC § 103**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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Claims 12-14, 16-22, 28-29, and 39 are newly rejected under 35 U.S.C. 103(a) as being unpatentable over Rosell et al (Rosell et al, Experimental approach to optimize the use of alpha-amylases in breadmaking, Journal of agricultural and food chemistry 2001, 49 (6): 2973-2977), in view of Inagawa et al (Homeostasis as regulated by activated macrophage. II. LPS of plant origin other than wheat flour and their concomitant bacteria, Chem. Pharm. Bull. 40 (4) 994-997, 1992).

Rosell et al teach alpha-amylase from different origins (wheat, malted barley, fungi) are used extensively to improve bread making (see Abstract). Rosell et al teach alpha-amylases occur naturally in wheat flour (thus an edible plant, thus a food grain, thus a plant extract powder) but sometimes the endogenous activity is not sufficient to yield fermentable sugars, consequently, flours are frequently supplemented with exogenous alpha-amylases. Commercial alpha-amylases can be obtained from fungal, cereal, or microbial sources. They have different thermal stabilities: fungal alpha-amylase is the most labile, followed those from cereal, and the most stable are the alpha-amylases from bacterial sources (page 2973, 2<sup>nd</sup> column, 1<sup>st</sup> paragraph). Rosell et al state the effect of temperature on the activity of different alpha-amylases. Rosell et al teach the bacterial type alpha-amylase displayed a continuous increase of activity as the pH increased, until the pH reached 6.0 (thus a neutral pH) (page 2974, 2<sup>nd</sup> column, 2<sup>nd</sup> paragraph). Rosell et al teach in Figure 2, the influence of the temperature on the hydrolytic activities of various alpha-amylases is shown (from 20 to 40 degree C). As expected, the enzyme activity increased with the temperature, but the trend was different depending on the enzyme origin: the bacterial alpha-amylase showed the highest increase with the temperature. It is known that the bacterial alpha-amylase of intermediate thermal stability also exhibits the highest thermal

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stability, therefore it will be the enzyme with greatest activity during both the fermentation and initial baking steps (page 2974, 2nd column, 3rd paragraph).

Rosell et al do not explicitly teach the fermentation is performed at 37 degree C with neutral pH; neither do Rosell et al teach the plant contains a glucide with a polysaccharide nor the plant has a facultative anaerobic gram negative bacterium *Pantoea agglomerans*.

As evidenced by Inagawa et al, lipopolysaccharide (LPS) of plant origin other than that of wheat flour was surveyed. Concomitant bacteria possibly extracting in root of farm products can be considered to contribute of LPS of plant origin. Some LPS were derived from concomitant bacteria which had probably come from root. Three predominant bacteria have been isolated and identified; *Pantoea agglomerans*, *Enterobacter cloacae* and *Serratia ficaria*. These LPSs were purified and their chemical compositions were examined (see Abstract). *Pantoea agglomerans* is the most remarkable, since it accounts for 40-70% of all living bacteria in wheat bran and wheat flour and is persistently isolated from all kinds of wheat flour produced in districts as different as, Canada, USA, Australia and Japan (page 996, 2nd column, last column). Inagawa et al also teach, *Pantoea agglomerans* is a species of gram-negative soil bacterial ubiquitously distributed, especially in cotton-seed and wheat, and contributes to the growth of plant by nitrogen fixation and also by release of phosphorus (page 997, 1st column, 1st paragraph) (thus lives in a symbiotic relationship exclusively with a plant).

It is noted that wheat flours are supplemented with exogenous alpha-amylases during bread making fermentation in Rosell et al, it is necessarily that the wheat flours contain a glucide whose major component is a polysaccharide and a facultative anaerobic gram negative bacterium *Pantoea agglomerans* that lives in a symbiotic relationship exclusively with the plant (wheat

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flour) since Inagawa et al explicitly teach so. It is also noted that when wheat flours are supplemented with exogenous alpha-amylases, no component derived from an animal was used.

It would have been prima facie obvious for one of ordinary skill in the art at the time the invention was made to ferment wheat flour with exogenous alpha-amylase at 37 degree C with a neutral pH since Rosell et al teach the bacterial type alpha-amylase displayed a continuous increase of activity as the pH increased, until the pH reached 6.0 (thus a neutral pH); And Rosell et al also teach the enzyme activity increased with the temperature between 20-40 degree C. Since Rosell et al yielded beneficial results in bread making food industry, one of ordinary skill in the art would have been motivated to use the reference.

The intended use of the composition was analyzed for patentable weight. It is deemed that the preamble 'breathes life' into the claims in that the prior art product must not be precluded for use as a bath agent, a pharmaceutical, an immunopotentiating agent, or macrophage activator with the presence of polymyxin B. It is deemed that the composition disclosed by the cited reference is not precluded for carrying out the intended function of the claims.

From the teachings of the references, it is apparent that one of the ordinary skills in the art would have had a reasonable expectation of success in producing the claimed invention.

Thus, the invention as a whole is prima facie obvious over the references, especially in the absence of evidence to the contrary.

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection under Rosell et al.

### **Conclusion**

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Qiuwen Mi whose telephone number is 571-272-5984. The examiner can normally be reached on 8 to 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Qiuwen Mi/

Primary Examiner, Art Unit 1655